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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/623,791 | 07/21/2003 | Wes Johnson | 44864.I.1 | 6098 |
| 28078 | 7590 | 03/15/2006 | EXAMINER | |
| MAGINOT, MOORE & BECK, LLP CHASE TOWER 111 MONUMENT CIRCLE SUITE 3250 INDIANAPOLIS, IN 46204 | | | LEWIS, RALPH A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |
| DATE MAILED: 03/15/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/623,791 | JOHNSON ET AL. | |
| | Examiner | Art Unit | |
| | Ralph A. Lewis | 3732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 98-173 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 98-173 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Rejection based on 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 98-173 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

More particularly the disclosure at page 27 of the specification fails to provide a reasonable basis for the claim limitations that the specifically claimed "space under the tibial plateau between two generally opposed surfaces of the fractured tibia" is accessed or that the elements or wafers are stacked "in the general direction of the axis of the tibia."

Rejection based on 35 U.S.C. 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 126-168 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Independent claims 126 and 136 positively claim the "elements" and "wafers" as forming a structure in a patient's tibia. The structure is claimed as being positively connected with the human patient (see *In re Rohrbacher*, 128 USPQ 117 (CCPA 1960)). Claims that are directed to or include within their scope a human being are not considered patentable subject matter under 35 U.S.C. 101 since the grant of a limited, but exclusive property right in a human being is prohibited by the constitution. See 1077 OG 24 (April 21, 1987).

The examiner suggests language such as "adapted to form a structure between said opposing surfaces" and "adapted to generally extend in the direction of the axis of the tibia" to make it clear that applicant is not claiming the patient as part of the invention. Applicant's attention is directed to *In re Rohrbacher*, 128 USPQ 117 (CCPA 1960) for guidance in claim drafting

Obvious-type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 98-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-97 of U.S. Patent No. 6,595,998 in view of Reiley et al (US 6,066,154).

Applicant's earlier patented claims are directed to a method, device and kit for distracting two tissue bone surfaces (claim 1) which may be vertebra (claim 37) with a plurality of wafers that are stacked consecutively in a column between the two tissue surfaces, but fails to claim the use of the method/device for fractured tibia's as is required by the currently pending claims. Reiley et al, however, teaches that for a similar device that it can be used of not only vertebra (Figure 11), but also fractured tibia (Figure 19). To have merely adapted and used the patented '988 method/device for tibia fractures in addition to fractured vertebra as taught by Reiley et al would have been obvious to one of ordinary skill in the art. Additionally, it is noted, that merely setting forth the previously patented wafers in the broader terms of "elements" would have been an obvious convention manner of claim drafting.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 126-132, 134-143, 158, 162 and 169-173 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantigan (US 5,192,327).

Assuming in regard to independent claims 126 and 136, that applicant is not intending to actually claim the patient and his/her tibia as part of the invention, then Brantigan discloses an apparatus comprised of a plurality of stackable wafers capable of being positioned within a patient's tibia in a column. The particular purpose for which applicant intends for the claimed wafers to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Brantigan.

Claims 126-128, 131, 133, 172 and 173 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US 5,702,454).

Assuming in regard to independent claim 126 that applicant is not intending to actually claim the patient and his/her tibia as part of the invention, then Baumgartner discloses an apparatus comprised of a plurality of elements 7 capable of being positioned within a patient's tibia to support and distract fractured surfaces of a tibia. The particular purpose for which applicant intends for the claimed elements to be used fails to impose any objectively ascertainable structural distinctions from the device disclosed by Baumgartner.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98-103, 105, 106, 126-128, 131, and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (US 5,702,454) in view of Reiley et al (US 6,066,154).

Baumgartner discloses an apparatus comprised of a plurality of elements 7 for distracting and supporting fractured vertebra, but fails to disclose the use of the method/device for fractured tibia's as is set forth in the currently pending claims. Reiley et al, however, teaches that for a similar device that it can be used of not only fractured vertebra (Figure 11), but also fractured tibia (Figure 19). To have merely used the Baumgartner method/device for tibia fractures in addition to fractured vertebra as taught by Reiley et al would have been obvious to one of ordinary skill in the art.

Claims 98-104, 107-112, 117-119, 121, 124-128, 132, 134-143, 158, and 162-165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (US 5,192,327) in view of Reiley et al (US 6,066,154).

Brantigan discloses an apparatus comprised of a plurality of stackable wafers used for distracting and supporting fractured vertebra, but fails to teach the use of the method/device for fractured tibia's as is set forth in the currently pending claims. Reiley et al, however, teaches that for a similar device that it can be used of not only fractured vertebra (Figure 11), but also fractured tibia (Figure 19). To have merely used the

Baumgartner method/device for tibia fractures in addition to fractured vertebra as taught by Reiley et al would have been obvious to one of ordinary skill in the art.

Prior Art

Applicant's information disclosure statements of July 21, 2003, November 10, 2003, October 12, 2004 and September 09, 2005 have been considered and initialed copies enclosed herewith.

Stone et al (US 6,387,130) and Manzi et al (US 6,997,929) are made of record.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (571) 272-4720.

R.Lewis
March 10, 2006



Ralph A. Lewis
Primary Examiner
AU 3732